

Diagnostic Immunology Page 1

Instructions: Complete in full for testing you personally performed, supervised and/or directed. Obtain all appropriate signatures and submit this form along with any applicable letters of documentation to the NYS Department of Health at the address listed above.

Name _____ CQ Code (if known) _____

Name of facility _____ PFI/CLIA# _____

Analyte (list under appropriate discipline)	Dates MM/YY-MM/YY	Volume for dates listed	Method/chemistry	Instrument/platform	FDA Approved* Yes/No
General Immunology (add additional page(s) if needed)					
Autoimmune Analytes (add additional page(s) if needed)					
Infectious Disease Serology (add additional page(s) if needed)					

*FDA-Approved assays include those cleared (510k), approved (PMA), exempted, or with Emergency Use Authorization (EUA) by the United States Food and Drug Administration (FDA) that have not been modified to change the procedure or the intended use. Investigational Use Only (IUO)-labeled tests are ONLY included when utilized under a specific FDA Investigational Device Exemption (IDE).

Is/Was all testing listed in the above table performed under your direct supervision? Yes No

If No, what percentage was under your direct supervision? _____ Under whose direct supervision (physician or doctoral level director) is/was the remaining testing performed? _____

**NEW YORK STATE DEPARTMENT OF
HEALTH**

Clinical Laboratory Evaluation Program
Wadsworth Center
Empire State Plaza
Albany, NY 12237

E-mail: CLEPCQ@health.ny.org

Web: www.wadsworth.org/regulatory/clep

Certificate of Qualification Questionnaire

**Diagnostic Immunology
Page 2**

Describe your responsibilities with respect to serology testing:

The applicant and supervisor/director must print and sign their names below to attest that the testing above was performed by and/or under direct supervision by the applicant.

_____	_____	_____
Print applicant name	Applicant signature	Date

_____	_____	_____
Print supervisor/director name	Supervisor/director signature	Date

Supervisor/director's relationship to applicant (e.g. direct supervisor) and how this allows attestation of the applicant's training and/or experience